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# (12) UK Patent Application (19) GB (11) 2 318 058 (13) A

(43) Date of A Publication 15.04.1998

(21) Application No 9619943.5

(22) Date of Filing 25.09.1996

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(51) INT CL<sup>6</sup>  
A61F 2/28, A61B 17/38, B21J 15/38

(52) UK CL (Edition P)  
A5R RAP RAT  
B3U U1E U1N

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(58) Field of Search  
UK CL (Edition O) A5R RAP RAT  
INT CL<sup>6</sup> A61B 19/00, A61F 2/02 2/28  
ONLINE: WPI

## (54) Three-dimensional modelling of maxillofacial implants

(57) A maxillofacial implant 18 to replace damaged or diseased bone is constructed by producing a three-dimensional digital representation of the region of interest by CAT scan then using the digital representation to create a model by stereolithography. This model can then be used to develop and fit the final implant 18. Also disclosed is a surgical rivetting tool (see Figure 6) having a C-shaped frame with a compression screw. Also disclosed is a connector block (see Figure 7) for implantation comprising a titanium body with rivet passages and also posts for attachment of dental prostheses.

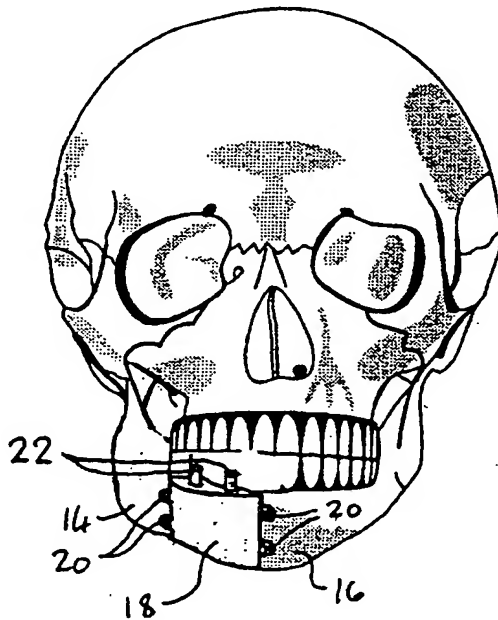


Fig. 4B

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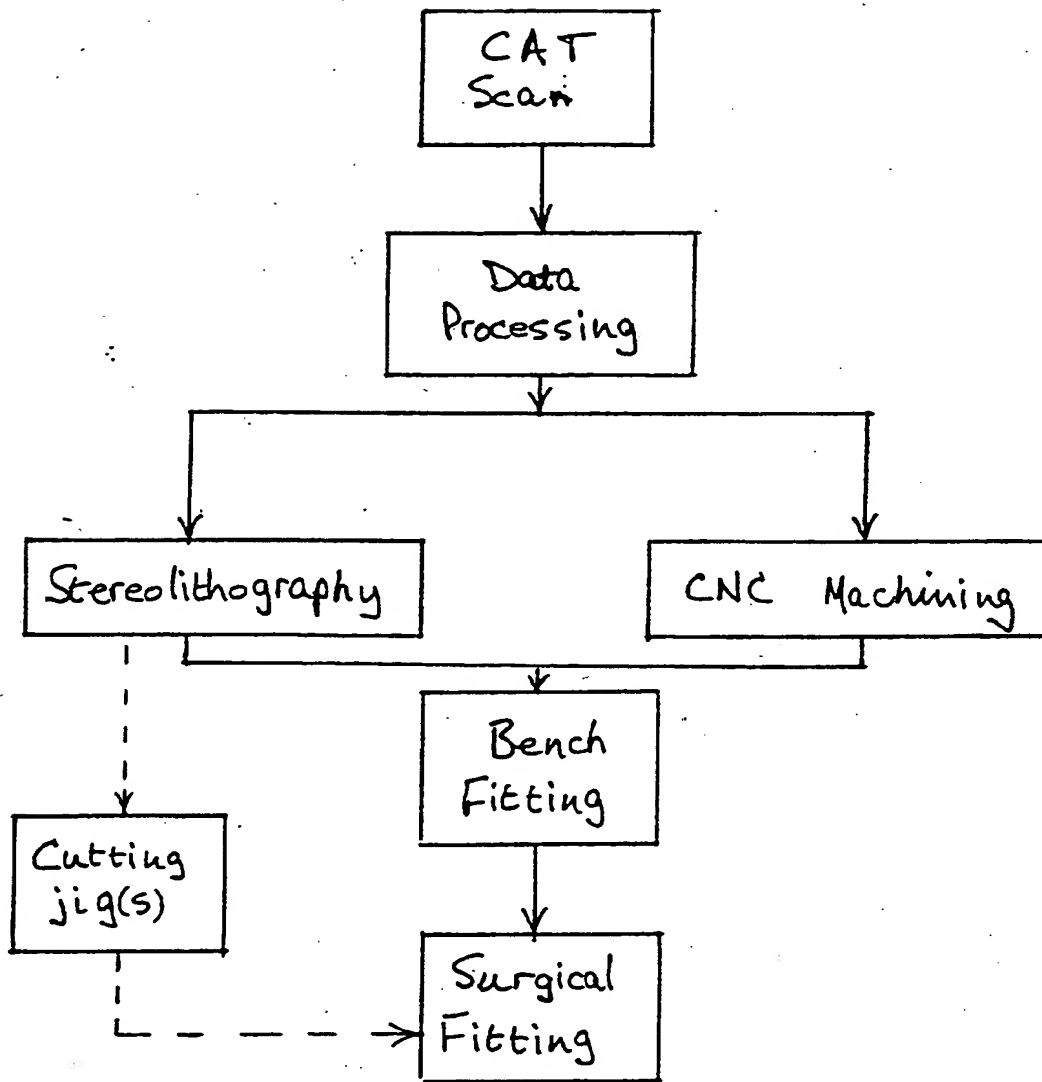


FIG. 1

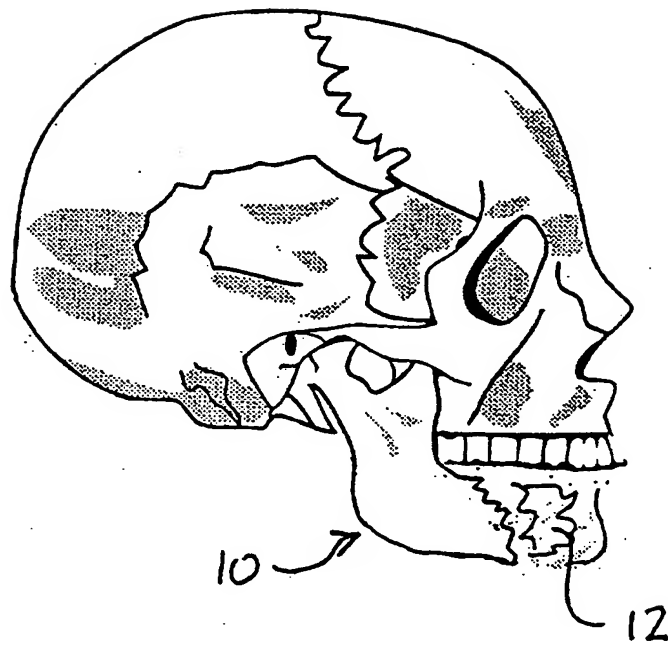


FIG. 2A

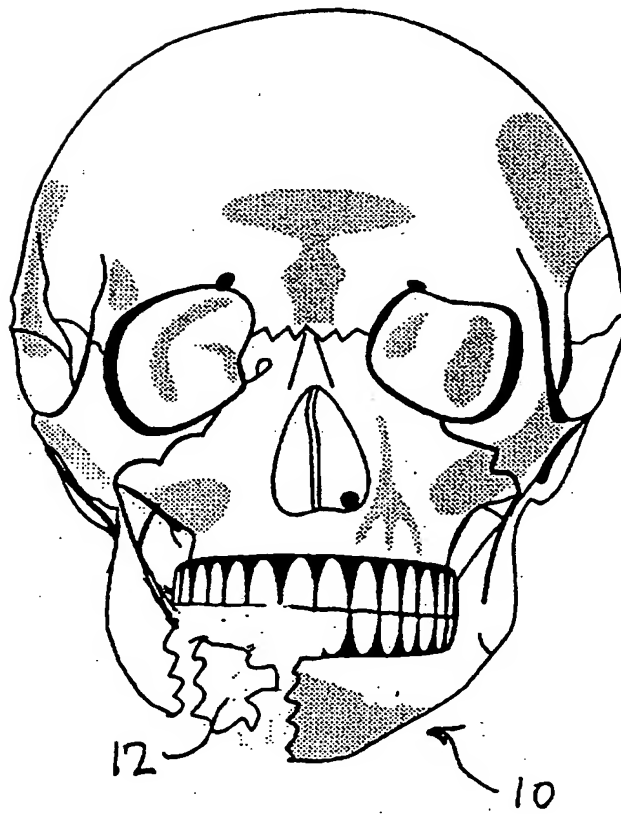


FIG. 2B

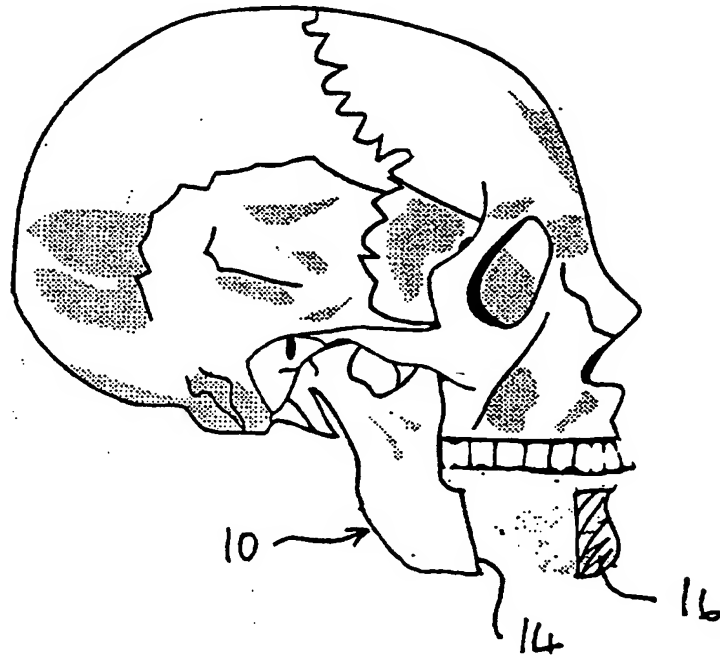


FIG. 3A

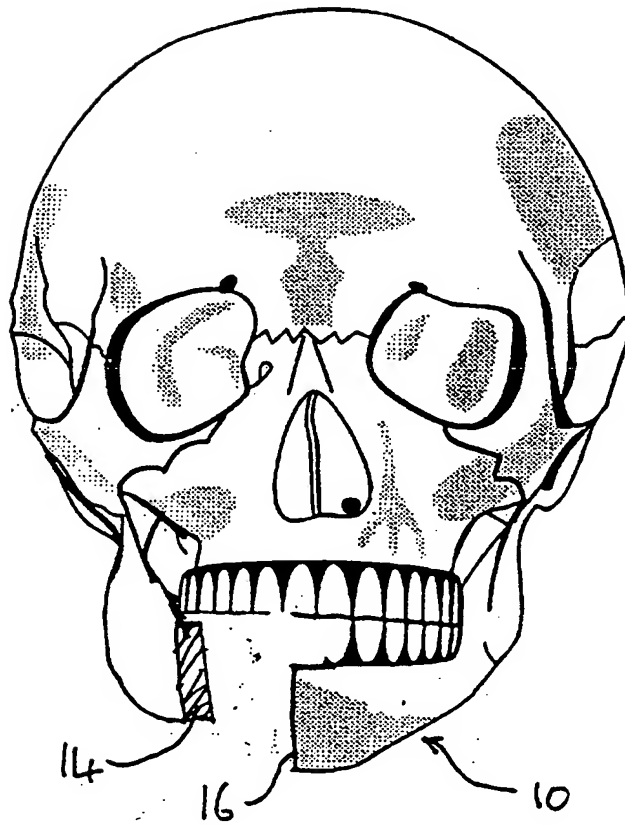


FIG. 3B

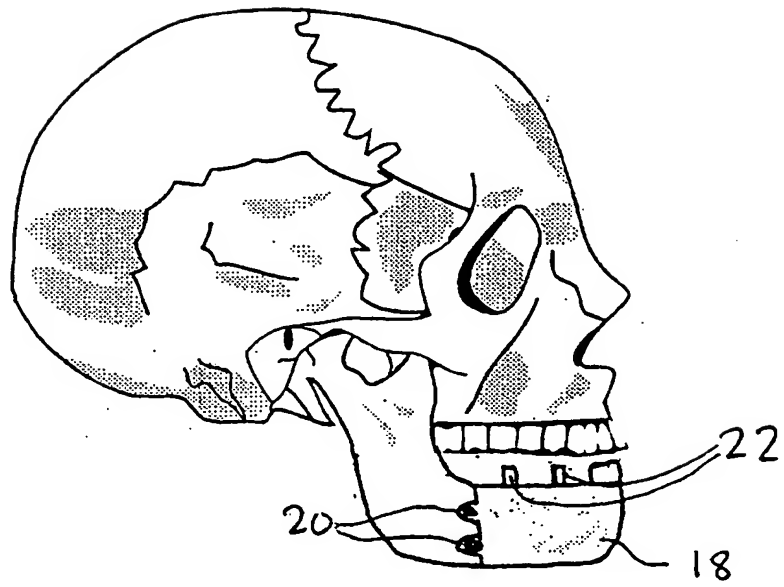


FIG. 4A

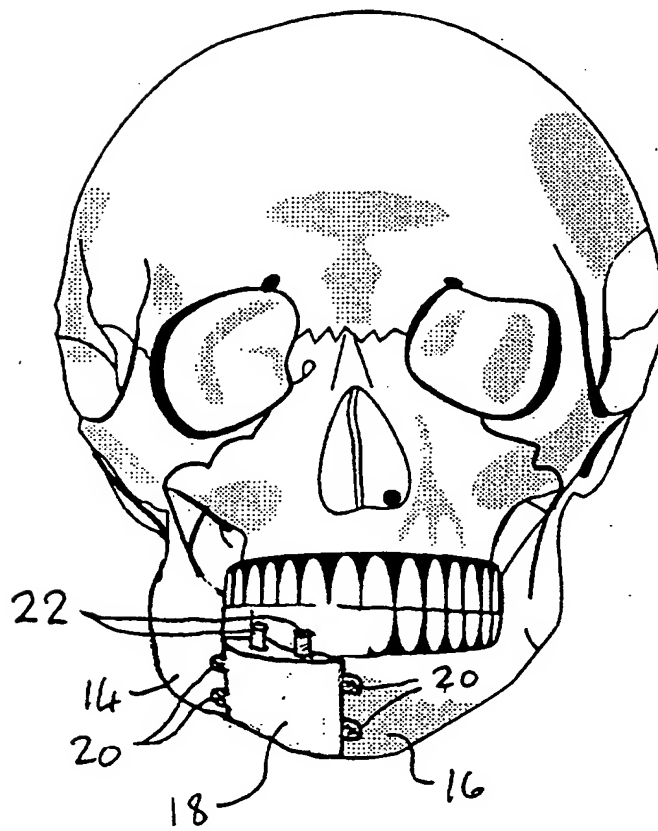


FIG. 4B

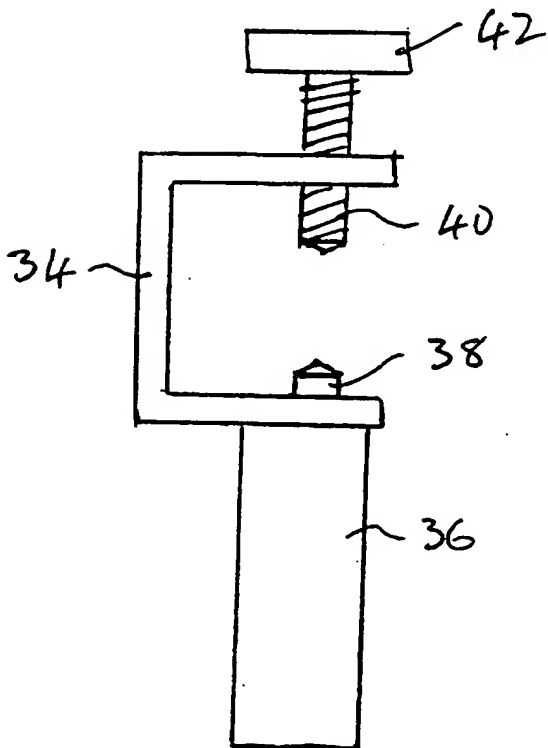
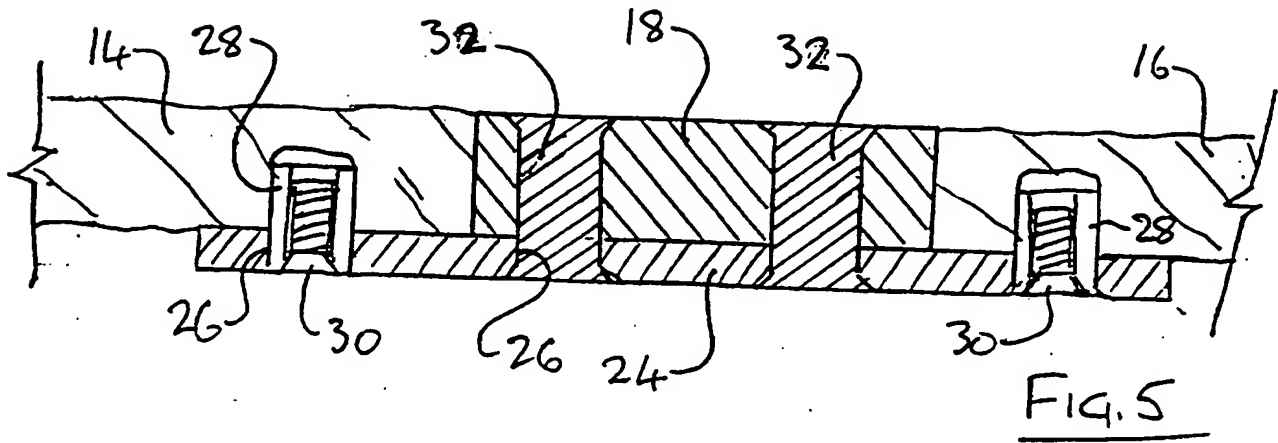


FIG. 6A

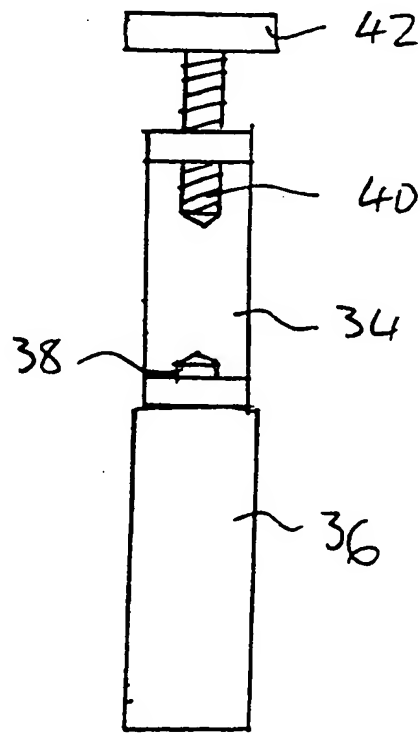
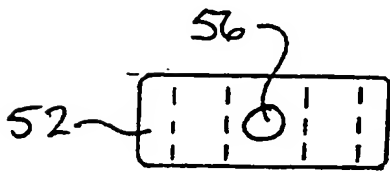
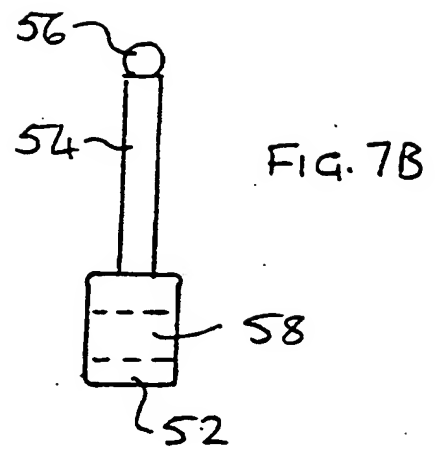
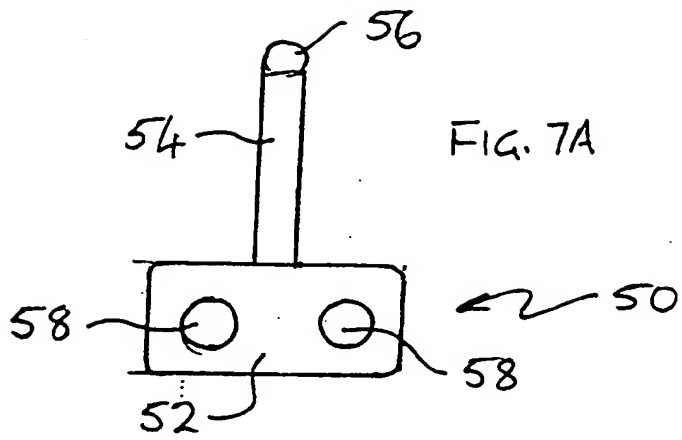


FIG. 6B



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1     "Improvements Relating to Prosthetic Implants"  
2

3     This invention relates to an improved method of making  
4     prosthetic implants, methods of treatment incorporating  
5     the use of such implants, and to the prosthetic  
6     implants themselves.  
7

8     The invention is of particular usefulness in relation  
9     to maxillofacial surgery and will be particularly  
10    described with reference to that field, but may also be  
11    utilised in the treatment of disease or damage in other  
12    parts of the body.  
13

14    Maxillofacial surgery may be necessary to deal with  
15    congenital defect, accidental damage, or malignant  
16    tumours. Such surgery presents particular difficulties  
17    since the aim is to achieve a result which is not only  
18    functional in dealing with the particular problem  
19    addressed, but also ensures that a patient is left with  
20    a good level of ability to breath, eat and speak, while  
21    at the same time achieving a satisfactory aesthetic  
22    appearance.  
23

24    Techniques are known in which diseased or damaged bone  
25    is excised and replaced. The replacement may be by way



1 of grafting bone taken from other parts of the  
2 patient's body. More recently replacement bone has  
3 been achieved by attaching a titanium armature to sound  
4 bone to act as a support for grafted bone cells derived  
5 from bone in other parts of the patient's body. In  
6 either case, it is then necessary to attempt to reform  
7 the adjacent soft tissue over the resulting implant.

8  
9 Another known technique is the use of microvascular  
10 free transfer osseofasciocutaneous flaps, in which a  
11 flap of bone and skin, for example from the forearm and  
12 optionally with attached muscle, is transferred to the  
13 mouth, with the blood vessels of the flap being  
14 connected to those of the head by microscopic surgery.  
15 A functional result may be achieved, but is non-  
16 anatomical.

17  
18 Such techniques are extremely time consuming and  
19 difficult. A typical maxillofacial repair may require  
20 a surgical procedure lasting up to about 15 hours, and  
21 the procedure will involve opening a second surgical  
22 site (typically in the region of the iliac crest) to  
23 obtain bone or bone cells for grafting.

24  
25 An object of the present invention is to enable  
26 reconstructive surgery of this nature to be carried out  
27 much more rapidly, thus markedly reducing the stress on  
28 the patient caused by the surgery, while reducing the  
29 load on the surgical team and also markedly reducing  
30 the costs of the surgery.

31  
32 In accordance with one aspect of the present invention,  
33 a method of making a prosthetic implant comprises the  
34 steps of obtaining a set of data defining the body  
35 parts of interest in three dimensions, using said set  
36 of data to create a three dimensional model of at least

1 part of the body parts of interest, and using the three  
2 dimensional model to develop and fit to size a  
3 prosthetic implant which entirely replaces body parts  
4 which are missing or are to be excised from the  
5 patient.

6

7 The invention also provides a prosthesis made by the  
8 foregoing method.

9

10 From another aspect, the invention provides a method of  
11 treating damaged, diseased or missing body parts which  
12 comprises excising damaged and/or diseased body parts  
13 and selected adjacent parts, and replacing excised  
14 and/or missing parts entirely by a prosthetic implant  
15 secured to the sound adjacent bone structures. In the  
16 preferred form of the method, both bone and soft tissue  
17 are replaced by a single prosthetic implant made of a  
18 material onto the surface of which soft tissue is  
19 capable of growing in a manner to prevent the incursion  
20 of infection; such a material will typically be  
21 titanium.

22

23 The foregoing method is preferably carried out by  
24 obtaining a set of data defining the body parts of  
25 interest in three dimensions, using said set of data to  
26 create a three dimensional model of at least part of  
27 the body parts of interest, and using the model to  
28 develop and fit to size the prosthetic implant prior to  
29 surgery.

30

31 In preferred forms of the invention the prosthesis  
32 extends through a body surface such as skin or mucous  
33 membrane, for example in the palate or nasal cavity.

34

35 The prosthetic implant may be provided with mechanical  
36 attachment means for the releasable attachment of

1 further prosthetic devices such as dentures.

2

3 The set of data defining the body parts of interest is  
4 preferably reduced by CAT scanning. The data resulting  
5 from the CAT scanning may be manipulated by computer,  
6 for example to derive from a CAT head scan a set of  
7 data defining three dimensionally only the bony  
8 structures of the skull.

9

10 The three dimensional model may conveniently be  
11 produced by stereolithography in a manner known per se  
12 by laser irradiation of a photoreactive polymer.

13

14 The present invention also provides a surgical  
15 rivetting tool comprising a C-shaped frame having a  
16 base and two limbs extending from the base, one limb  
17 carrying an anvil and the other carrying a compression  
18 member movable toward and away from the anvil. The  
19 compression member may be a screw in threaded  
20 engagement with said other limb and operated by a  
21 thumbwheel.

22

23 A further aspect of the invention provides a connector  
24 block comprising a body and a post extending from the  
25 body, the post being shaped for selective attachment to  
26 dental prostheses, and the body being formed with  
27 passages for rivets for attachment to a surgical plate.

28

29 Preferably, the body is rectangular, and the connector  
30 block is formed integrally from titanium.

31

32 Embodiments of the invention will now be described, by  
33 way of example only, with reference to the drawings, in  
34 which:

35 Fig 1 is a flow chart illustrating the method of  
36 the present invention;

1 Figs 2a and 2b are schematic views in side and  
2 front views respectively of a skull having an area of  
3 damage in the lower jaw;

4 Figs 3a and 3b are similar view of the skull with  
5 the damaged area excised;

6 Figs 4a and 4b are similar views of the same skull  
7 with a prosthesis implanted;

8 Fig 5 is a schematic side view of an alternative  
9 mounting arrangement;

10 Fig 6A is a side view of a rivetting tool;

11 Fig 6B is a front view of the rivetting tool; and

12 Fig 7A, 7B and 7C are respectively side, end and  
13 plan views of a connector block embodying a further  
14 aspect of the invention.

15

16 Referring to Fig 1, the process of the present  
17 invention is based upon the use of a CAT scan to derive  
18 a set of data defining in three dimensions the body  
19 part of interest, for example the skull. Accordingly,  
20 a conventional CAT scan provides data to a data  
21 processing step in which the data defining the bony  
22 structures are retained and the soft structure data  
23 discarded.

24

25 The processed data is then used to produce a replica of  
26 the patient's skull by stereolithography. There are  
27 techniques well known per se for the production of  
28 three dimensional models from digital data by  
29 stereolithography by laser irradiation of a bath of  
30 photoreactive polymer. In this way, a model of the  
31 patient's skull in its existing form is obtained.

32

33 The data from the CAT scan can also be processed to  
34 provide a further set of data defining in three  
35 dimensions a desired replacement part. This further  
36 data is then used to produce a replacement part by CNC

1 machining from solid titanium.

2

3 At this stage, the surgical team have a true scale  
4 model of the existing skull plus a machined replacement  
5 for part of the skull. These can be used in the  
6 workshop (that is, in non-surgical, non-sterile  
7 conditions) to refine the surgical operation to be  
8 performed. In particular, the surgeon can plan the  
9 best positions to cut to obtain sound bone on which to  
10 mount the implant. The cutting and mounting can be  
11 performed experimentally on the model skull, and the  
12 shape of the machined implant can be refined in this  
13 process.

14

15 Optionally, as indicated in Fig. 1, during the workshop  
16 stage cutting jigs may be produced which are located  
17 with respect to well-defined points on the skull and  
18 provide a guide to enable the surgeon to cut the bone  
19 accurately in the planned planes.

20

21 Once the surgical plan and prosthetic implant have been  
22 refined in the workshop, the prosthesis is implanted  
23 surgically in the conventional manner. Typically, the  
24 prosthesis will be secured to sound bone by means of  
25 bone screws or expansion-type fixings.

26

27 An important feature of the present invention is that  
28 the prosthesis is of a material, typically titanium,  
29 which is compatible with passing through the surface of  
30 soft tissue without permitting the ingress of infection  
31 along the exposed surface of the implant. This allows  
32 the prosthesis to be a complete replacement for excised  
33 parts.

34

35 For example, in the case where part of the upper or  
36 lower jaw or the palate must be removed, the parts

1 removed are replaced only by the implant, without  
2 attempting to separate and then reposition the soft  
3 tissue of the gum or palate. This is not only much  
4 less time consuming in surgery, but also makes the  
5 surgical site functional much more quickly post-  
6 operatively.

7  
8 Figs. 2 to 4 illustrate such a procedure schematically  
9 with reference to a damaged lower mandible.

10  
11 As seen in Fig. 2 a lower jaw 10 has an area of damage  
12 involving both the jaw and the teeth. Fig. 3  
13 illustrates the damaged area cut back to sound bone at  
14 14 and 16. In Fig 4, a solid implant 18 of titanium  
15 has been attached to the sound bone areas 14, 16 by  
16 bone screws 20. The implant 18 is provided with posts  
17 22 to which a denture may be directly mounted. It will  
18 be understood that the implant 18 extends into the  
19 interior of the patient's mouth, within which it will  
20 be visible, and the margin of the healthy, non-excised  
21 gum will grow onto the surface of the implant.

22  
23 The stages of Figs. 2 to 4 will be carried through  
24 first in the workshop on the model skull, and only  
25 thereafter on the patient surgically.

26  
27 For simplicity of description, Fig 4 shows the implant  
28 18 being attached by simple bone screws 20. In view of  
29 the loads typically placed on the mandible, it is  
30 preferable to obtain a more secure mechanical  
31 engagement. One such arrangement is illustrated in Fig  
32 5. The implant 18 is secured (for example, rivetted or  
33 welded) to a plate 24 which in turn is attached to the  
34 sound bone areas 14, 16, to lie along the underside of  
35 the mandible. The example shown makes use of a "Thorp"  
36 plate which has regularly spaced apertures 26. The

1 plate 24 is attached to the bone by fasteners which  
2 comprise a titanium cylinder 28 passed through one of  
3 the apertures 26 into a bore drilled in the bone, and a  
4 screw 30 engaging internally in the cylinder 28 to  
5 produce a wedging effect. This arrangement is less  
6 prone to loosen than bone screws, and copes well with  
7 bone regrowth.

8  
9 The implant 18, in the example of Fig 5, is secured to  
10 the plate by titanium rivets 32.

11  
12 In a modification (not shown), the implant may be made  
13 in a modular fashion, with the total volume to be  
14 replaced being provided by a number of interfitting  
15 parts which may, for example, be secured to a common  
16 mounting plate such as the plate 24 of Fig 5. This  
17 arrangement may simplify the surgical procedure in  
18 certain cases.

19  
20 Fig 6 illustrates a rivetting tool suitable for use  
21 with the embodiment of Fig 5. A C-shaped frame 34  
22 mounted on a handle 36 carries an anvil 38 and an  
23 opposed screw 40 operated by a thumbwheel 42.

24  
25 Fig 7 shows a connector block 50 which may be used with  
26 the embodiments described above, or for other  
27 applications.

28  
29 The block 50, which is machined from solid titanium,  
30 has a rectangular body 52 with an upstanding post 54.  
31 The top of the post 54 is formed into a part-sphere 56  
32 for attachment of dentures, bridgework, etc.

33  
34 The body 52 is formed with parallel, circular passages  
35 58 which enable the connector block 50 to be connected  
36 to an apertured device such as a "Thorp" plate by

1 rivets, as in Fig 5, which may be secured by the tool  
2 of Fig 6.

3

4 The part-sphere 56 is suitable for certain known types  
5 of connection. It may be replaced by alternative  
6 formations at the top of the post, for example for  
7 cooperation with screw-type connections.

8

9 Modifications and improvements may be made to the  
10 foregoing within the scope of the present invention.

11

12

13



CLAIMS

1. A method of making a prosthetic implant comprising the steps of:
  - obtaining a set of data defining the body parts of interest in three dimensions,
  - using said set of data to create a three dimensional model of at least part of the body parts of interest, and
  - using the three dimensional model to develop and fit to size a prosthetic implant which entirely replaces body parts which are missing or are to be excised from the patient.
2. A method of treating damaged, diseased or missing body parts which comprises excising damaged and/or diseased body parts and selected adjacent parts, and replacing excised and/or missing parts entirely by a prosthetic implant secured to the sound adjacent bone structures.
3. The method of claim 2, in which both bone and soft tissue are replaced by a single prosthetic implant made of a material onto the surface of which soft tissue is capable of growing in a manner to prevent the incursion of infection.
4. The method of claim 3, in which said material is titanium.
5. The method of any of claims 2 to 4, carried out by obtaining a set of data defining the body parts of interest in three dimensions, using said set of data to create a three dimensional model of at least part of the body parts of interest, and

- 1           using the model to develop and fit to size the  
2           prosthetic implant prior to surgery.  
3
- 4       6.    The method of claim 1 or any of claims 2 to 5, in  
5           which the prosthetic implant extends through a  
6           body surface such as skin or mucous membrane.  
7
- 8       7.    The method of claim 6, in which said body surface  
9           is the palate or nasal cavity.  
10
- 11      8.    A prosthetic implant made by the method of any of  
12           claims 2, 5, 6 and 7.  
13
- 14      9.    The prosthetic implant of claim 8, provided with  
15           mechanical attachment means for the releasable  
16           attachment of a further prosthetic device.  
17
- 18      10.   The prosthetic implant of claim 9, in which said  
19           further prosthetic device is a denture.  
20
- 21      11.   The method of claim 1 or claim 6, in which the set  
22           of data defining the body parts of interest is  
23           produced by CAT scanning.  
24
- 25      12.   The method of claim 11, in which the data  
26           resulting from the CAT scanning is manipulated by  
27           computer.  
28
- 29      13.   The method of claim 12, in which the data is  
30           manipulated to derive from a CAT head scan a set  
31           of data defining three dimensionally only the bony  
32           structures of the skull.  
33
- 34      14.   The method of claim 13, in which a three  
35           dimensional model may conveniently is produced  
36           from aid data by stereolithography.

- 1 15. A connector block for use in maxillofacial  
2 surgery, the connector block comprising a body and  
3 a post extending from the body, the post being  
4 shaped for selective attachment to dental  
5 prostheses, and the body being formed with  
6 passages for rivets for attachment to a surgical  
7 plate.  
8  
9 16. The connector block of claim 15, in which the body  
10 is rectangular, and the connector block is formed  
11 integrally from titanium.  
12